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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,870	11/04/1999	WILLIAM D. HUSE	P-IX-3458	4474

23535 7590 04/29/2003

MEDLEN & CARROLL, LLP
101 HOWARD STREET
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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/29/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/434,870

Applicant(s)

HUSE ET AL.

Examiner

Larry R. Helms

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. The request filed on 2/5/03 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/434,870 is acceptable and a RCE has been established. Claims 42-71 are pending and are currently under prosecution. An action on the RCE follows.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

4. The rejection of claims 42-71 under 35 U.S.C. 103(a) as being unpatentable over Deng et al (Canadian Patent 2,125,240 A1, published 12/7/95, IDS #8) and further in view of Yelton et al (The Journal of Immunology 155:1994-2004, 1995) and Hagiwara et al (U.S. Patent 5,589,573, issued 12/1996) is withdrawn in view of arguments and the declaration of Dr. Watkins.

The following are some NEW GROUNDS of rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 42, 44-47, 49-52, 54-57, 59-62, 64-67, 69-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Aruffo et al (U.S. Patent 6,312,693, filed 2/1999).

The claims recite a method of constructing a population of heavy or light chain variable region encoding nucleic acids comprising providing a donor sequence and an acceptor sequence and chemically synthesizing a population of oligos encoding for at least one modified CDR and one modified framework residue wherein at least one amino acid is different from the reference sequence and mixing to create overlapping oligos and constructing the nucleic acids. Further co expressing the population with a light or heavy chain and wherein the acceptor is human and further the method comprises extending the oligos with polymerase.

Aruffo et al teach a method of constructing a library of heavy or light chain regions wherein one CDR is mutated and the frameworks are also modified simultaneously relative to the reference human sequence and expression of the heavy and light chains and the oligos are overlapping and extended by PCR (see column 27-28).

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7. Claims 42-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aruffo et al (U.S. Patent 6,312,693, filed 2/99) as applied to claims 42, 44-47, 49-52, 54-57, 59-62, 64-67, 69-71 above, and further in view of Hagiwara et al (U.S. Patent 5,589,573, issued 12/96).

Claims 42, 44-47, 49-52, 54-57, 59-62, 64-67, 69-71 have been described supra. Claims 43, 48, 53, 58, 63, 68 recite wherein the visual representations of the first and the second reference sequences are in electronic form.

Aruffo et al has been described supra. Aruffo et al does not teach the reference sequence in electronic form. This deficiency is made up for in the teachings of Hagiwara et al.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have the first and second reference sequences to be in electronic form.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have the first and second reference sequences to be in electronic form because Hagiwara et al teach amino acid sequences from a data base of Kabat et al and the sequences are retrievable by computer (see column 12, lines 25-40). In addition, because the database is accessible by computer it would be obvious to download the sequences onto an electronic form for storage and manipulation.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.
10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



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